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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,468	03/09/2004	Leo B. Kriksunov	2004.10LK	2287
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PASTEL LAW FIRM CHRISTOPHER R. PASTEL 8 PERRY LANE ITHACA, NY 14850-9267			EXAMINER GRAY, PHILLIP A	
			ART UNIT	PAPER NUMBER
			3767	
			MAIL DATE	DELIVERY MODE
			06/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/796,468

Applicant(s)

KRIKSUNOV, LEO B.

Examiner

Phillip Gray

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to applicant's communication on 3/4/2007.
Currently elected claims 1-9 are pending and stand rejected below.

Response to Arguments

Applicant's arguments filed 3/4/2007 have been fully considered but they are not persuasive.

Applicant argues that the prior art fails to teach, "any detection of the success of jet injection based on differentiation of conductivity through a jet which has penetrated the skin vs. the jet that has failed to penetrate the skin of the patient..". Applicant argues that Wariar et al. does not disclose measuring impedance through a "jet of liquid". In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "measurement of impedance through the jet of liquid") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is recommended that applicant add this claim limitation to greater clarify and further define there invention if that is where they feel their novelty lies.

Further applicant argues that it would not be obvious for a jet injector to be an access device, and that if a jet injector was the access device for Wariar extreme blood

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spillage would occur during its dialysis therapy operation. It is examiners position that dialysis therapy is just one of the operations that Wariar teaches. Wariar also teaches medication delivery (see abstract and column 4 line 27) and the use of a jet injection device would not destroy the teaches of Wariar for medication delivery and its operations and methods. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As stated in the rejection below the elements and method steps disclosed in Wariar et al. are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper. It is recommended that applicant amend the claims to specify that the impedance is measured directly through the jet of fluid to greater distinguish over Wariar.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wariar et al. (U.S. Patent Number 7,138,088). Wariar discloses and teaches a method for a direct contact measurement to detect access disconnection such as dislodgement of an access device from the patient through which fluid can flow during medication delivery therapy. Further Wariar teaches a method of delivering a drug into a patients body through a patient's skin (as in figure 1C) with an injection device (device from 68,64,66,70, to 56), forming an electrical circuit between the patients body and the injection device (as shown in figure 1c and arrow), providing an electric impedance monitor (such as element at 74) and measuring the electrical impedance between the patients body and the injection device, delivering the drug (fig. 1c), and detecting the change in impedance during the delivery of the drug into the patients body (specifically see Wariar paragraphs at column 10-12), further causing a audible and/or visual signal that indicates the change in the electric circuit impedance (see column 17 line 22).

Wariar discloses the claimed invention except for using a jet injection device as an injection device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a jet injection device as an injection device since it was known in the art that providing an injection by a jet form is one type hypodermic injection. It is examiners position that it would be implicit in Wariar that a jet type of injection is encompassed in the term access device or injection device and if not implicit an obvious variation thereof. It would be obvious to modify the injection device, (in the fig 1c a needle) with a jet injector since this would provide an alternate equivalent mode of delivering fluid to a patient.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



PAG

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

